

09-25-00

A

FORM PTO-1082

Case Docket No. 4042-A3

Commissioner of Patents and Trademarks  
Box Patent Application  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the utility patent application of:

Inventor: TERRY L. RAY  
Entitled: VERTEBRAL DRILL BIT AND INSERTER

Enclosed are:

X 22 sheets of specification and claimsX 3 sheet(s) of drawings and 3 copies of same       An Assignment of the invention to: \_\_\_\_\_.X Declaration and Power of Attorney (X)Executed ( )UnexecutedX Verified statement(s) to establish Small Entity Status under 37 CFR 1.9 and 37 CFR 1.27X Information Disclosure Statement       Also enc.: \_\_\_\_\_.

The filing fee has been calculated as shown below:

(Col. 1)		(Col.2)	SMALL ENTITY		LARGE ENTITY	
FOR:	NO. FILED	NO. EXTRA	RATE	FEE	RATE	FEE
BASIC FEE:	1		X380 =	\$345	X760 =	690
TOTAL CLAIMS:	17 - 20 =		X 9 = \$	or	X 18 = \$	
INDEP CLAIMS:	2 - 3 =		X 39 = \$	or	X 78 = \$	
MULTIPLE DEPEND CLAIM PRESENTED			X130 = \$	or	X260 = \$	
CHECK ENCLOSED:			TOTAL= \$345		TOTAL=\$	

       Please charge the Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.       The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. \_\_\_\_\_.       A duplicate copy of this transmittal sheet is enclosed.

Respectfully submitted,

*Robert A. Parsons*

Robert A. Parsons, Reg. No. 32,713

Date

9/22/00

09/22/00  
jc894 U.S. PTO

jc825 U.S. PTO  
09/668400  
09/22/00

09/22/00 09/22/00 09/22/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Terry L. Ray )  
Serial No.: )  
Filed: Herewith )  
Title: VERTEBRAL DRILL BIT AND )  
INSERTER )



CERTIFICATE OF EXPRESS MAILING

Honorable Commissioner of  
Patents and Trademark  
Washington, D.C. 20231

"Express Mail" mailing label number: EL686125284US  
Date of Deposit: 22 September 2000

Dear Sir:

I hereby certify that the attached Application Transmittal Form; Declaration and Power of Attorney, executed; Small Entity Statement, executed; Information Disclosure Statement; Application: Specification, fifteen (15) pages; Claims, five (5) pages; Abstract, one (1) page; three (3) sheet(s) informal drawings and three (3) copies of same; check for appropriate fees; and a postcard are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, Box PATENT APPLICATION on 22 September 2000.

Heidi Eckert  
Signature

22 September 2000  
Date

PARSONS & GOLTRY  
340 East Palm Lane  
Suite 260  
Phoenix, Arizona 85004  
  
(602) 252-7494

Respectfully submitted,

Robert A. Parsons  
Robert A. Parsons  
Attorney for Applicant  
Registration No. 32,713

Applicant or Patentee: Terry L. Ray  
Serial or Patent No.: Attorney's Reg. No.: 32,713  
Filed or Issued: Herewith Docket No.: 4042-A3  
For: VERTEBRAL DRILL BIT AND INSERTER

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(b)--INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled VERTEBRAL DRILL BIT AND INSERTER

described in

☒ the specification filed herewith  
\_\_\_\_\_ application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
\_\_\_\_\_ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern, or organization  
\_\_\_\_\_ persons, concerns or organizations listed below\*

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

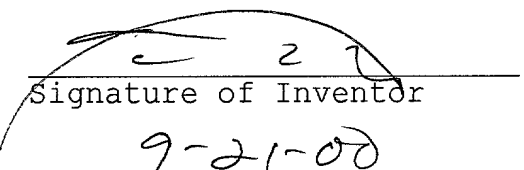
FULL NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
\_\_\_\_ Individual \_\_\_\_ Small Business Concern \_\_\_\_ Nonprofit Organization

FULL NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
\_\_\_\_ Individual \_\_\_\_ Small Business Concern \_\_\_\_ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Terry L. Ray  
Name of Inventor

  
Signature of Inventor

9-21-00  
Date

VERTEBRAL DRILL BIT AND INSERTER

Invented by

**Terry. L. Ray**

a resident of

1118 East San Angelo Avenue  
Gilbert, Arizona 85234

a citizen of  
the United States

1 VERTEBRAL DRILL BIT AND INSERTER

2  
3 FIELD OF THE INVENTION

4  
5 This invention relates to medical instruments.

6  
7 More particularly, the present invention relates to  
8 devices for spinal fixation

9  
10 In a further and more specific aspect, the instant  
11 invention concerns positioning and placement of pedicle screws.

12  
13 BACKGROUND OF THE INVENTION

14  
15 Injuries to the spinal column have always been numerous  
16 and debilitating. Only recently have techniques been developed  
17 to reduce effects of injuries and wear on the vertebrae.  
18 Spinal fixation employing screws inserted into the pedicles of  
19 the vertebrae is a well accepted technique. The force nucleus  
20 of the normal vertebrae is located at the base of the superior  
21 process at a point where the ridge on the pars  
22 interarticularis, the ridge on the superior facet, and the  
23 ridge on the transverse process all converge. Opening the  
24 cortical bone at this point permits access to the  
25 intermedullary canal of the pedicle through which the screw  
26 passes into the vertebral body. Generally, screws are inserted

1 into a number of vertebrae and fix plates in position for  
2 stabilization of a portion of the spinal column.

3  
4 Each screw is inserted by first locating the proper area  
5 either visually or by the use of a probe. When the proper  
6 location (force nucleus) is located, an opening is typically  
7 formed in the cortical bone using a rongeur or gouge. Once a  
8 portion of the cortical bone has been removed, a pedicle probe  
9 is employed to probe the pedicle. The probe is inserted with  
10 its tip perpendicular to the horizontal plane. A gentle back-  
11 and-forth or wiggle motion is used to advance the probe through  
12 the cancellous bone within the pedicle. It is desirous that  
13 the angled tip of the probe follow the cancellous tube of bone  
14 to the vertebral body. However, often the probe will sharply  
15 exit the pedicle. If this occurs, a ball tip probe must be  
16 employed outside the pedicle to determine if the probe has  
17 indeed exited the pedicle. This can be a serious problem if  
18 the probe exits into the vertebral foramen. Often the  
19 physician will manipulate the probe in such a manner as to  
20 insure that an exit does not occur into the vertebral foramen.  
21 This, however, often has the result of over compensation and an  
22 exit in a different location.

23  
24 After the probe reaches the vertebral body, the probe is  
25 withdrawn and a marker is inserted. Intraoperative x-rays are  
26 taken to confirm positioning, before the screws are inserted.  
27 After the exploratory probe has been completed, each pathway

1 must be widened with a tap of appropriate dimensions. The  
2 pedicle screw is then positioned.

3  
4 While effective, current placement of pedicle screws is  
5 time consuming due to the number of steps, including  
6 penetrating the cortex, probing the pedicle, confirming the  
7 positioning, tapping the pathway, and inserting the screw.  
8 Furthermore, the skill needed to perform this procedure,  
9 particularly the step of probing, is very great. While  
10 following the path of least resistance, namely the cancellous  
11 tube through the pedicle, sounds straight forward, it is very  
12 difficult. The cancellous tube is bone, and although less  
13 resistant than the cortex, still requires pressure to force the  
14 probe through. A great deal of "feel" and control is needed to  
15 avoid exiting the pedicle. Even with highly skilled  
16 individuals, many exits occur. While generally not injurious,  
17 this slows the process even more. There is also the chance of  
18 injury to the spinal cord and/or nerve roots if the exit occurs  
19 into the vertebral foramen. The high level of skill required  
20 and the time required translates into increased expense.

21  
22 It would be highly advantageous, therefore, to remedy the  
23 foregoing and other deficiencies inherent in the prior art.

24  
25 Accordingly, it is an object of the present invention to  
26 provide a new vertebral drill bit and inserter.



1           Another object of the invention is to provide a vertebral  
2 drill bit which is self guiding.

3

4           And another object of the invention is to provide a  
5 vertebral drill bit which will reduce exits from the pedicle.

6

7           Still another object of the present invention is to  
8 provide a vertebral drill bit which can be employed to confirm  
9 positioning.

10

11           Yet another object of the invention is to provide a  
12 vertebral drill which is relatively quick and easy to use.

SUMMARY OF THE INVENTION

Briefly, to achieve the desired objects of the instant invention in accordance with a preferred embodiment thereof, provided is a vertebral drill bit for forming a pathway through a pedicle into a vertebral body. The drill bit includes a cutting shank having a first end and a second end and a generally uniform diameter therebetween, an attachment head at the first end of the cutting shank and a tip at the second end of the cutting shank. Also provided is a point at which the diameter of the cutting shank at the second end begins to get smaller to form the tip. A flute is formed in the cutting shank and extends from the first end to the tip. An edge of the flute from the first end to proximate the point is sharp for cutting, and edges of the flute from the point to the tip are rounded.

Also provided in another embodiment is an inserter for coupling the drill bit to a drill. The inserter includes a chuck end and a receiver end.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and further and more specific objects and advantages of the instant invention will become readily apparent to those skilled in the art from the following detailed description of a preferred embodiment thereof taken in conjunction with the drawings, in which:

FIG. 1 is a perspective view of the drill bit and inserter of the present invention, as it appears forming a pathway in a pedicle;

FIG. 2 is an isometric view of the drill bit and inserter of FIG. 1 with portions thereof removed;

FIG. 3 is a partial sectional side view of the drill bit and inserter of FIGS. 1 and 2;

FIG. 4 is an exploded isometric view of the drill bit and inserter of FIGS. 1-3;

FIG. 5 is a view of another embodiment of an attachment shank of a drill bit;

FIG. 6 is a partial perspective view of the engagement elements of another embodiment of a drill bit and inserter; and

1           FIG. 7 is an exploded perspective view of another  
2   embodiment of a drill bit and inserter.

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

2

3 Turning now to the drawings in which like reference

4 characters indicate corresponding elements throughout the

5 several views, attention is first directed to FIG. 1 which

6 illustrates a drill bit 10 carried by an inserter 12 inserted

7 into a vertebrae 14. Drill bit 10 has formed a pathway through

8 a pedicle 15 of vertebrae 14. The pathway is well known to

9 those skilled in the art and includes an opening formed in the

10 force nucleus of vertebrae 14. The force nucleus is located at

11 the base of the superior process at a point where the ridge on

12 the pars interarticularis, the ridge on the superior facet, and

13 the ridge on the transverse process all converge. Opening the

14 cortical bone at this point permits access to the

15 intermedullary canal of the pedicle formed of cancellous bone.

16 When the proper location (force nucleus) is located, an opening

17 is formed in the cortical bone using any conventional technique

18 such as using a rongeur or gouge. Once a portion of the

19 cortical bone has been removed, the pathway is completed by

20 drilling through the cancellous bone to the vertebral body

21 using drill bit 10. Once the pathway has been formed, the

22 drill bit can be employed as a marker during an x-ray procedure

23 to confirm positioning. In this illustration inserter 12 is

24 employed to couple drill bit 10 to a drill (not shown). As

25 will become evident, various other inserters can be employed to

26 couple a drill bit to the drill, some of which will be

27 described as different embodiments. Additionally, different

embodiments of attachment structures for attaching the drill bit to the inserter will be described. Each will be employed in substantially the same manner as described herein.

Turning now to FIGS 2-4, drill bit 10 and inserter 12 are illustrated. Drill bit 10 includes a cutting shank 20 having an attachment head 22 at one end and a tip 23 at an opposing end. Cutting shank 20 flares proximate attachment head 22, to substantially match the diameter thereof. At least one flute 24 extends the length of cutting shank 20 from tip 23 to attachment head 22. Flute 24 has a sharp edge 25 extending its entire length except at tip 23. Both edges of flute 24 can be sharp if desired. Rounded or dull edges 27 are formed at tip 23 for purposes which will be described presently. The transition between sharp edge 25 and dull edges 27 is preferably located at a point 28 where tip 23 ends and cutting shank 20 reaches a substantially uniform or tapering width clearly definable from the greater slope of tip 23. It will be understood that sharp edge 25 can start further back toward attachment head 22, but not further forward toward tip 23. Flute 24 extends into the flared portion with cutting edge 25 also flaring.

When forming the pathway through pedicle 15, cutting edge or edges 25 cut through the cancellous bone following the intermedullary canal into the vertebral body. Dull edges 27 at tip 23 are incapable of cutting through cortical bone, and thus

1 will be deflected by the walls of pedicle 15. Drill bit 10  
2 will therefore remain within the intermedullary canal and not  
3 exit through the wall of pedicle 15. In this manner, a self  
4 guiding drill bit is provided. As mentioned previously, drill  
5 bit 10 is started in the pedicle through an opening formed  
6 through the cortical bone using conventional methods. The  
7 flared portion of cutting shank 20 and the corresponding flared  
8 portion of sharp edge 25 form a counter sink in the cortical  
9 bone. This is formed to receive the intergal nut of  
10 conventional screws used in this procedure. It also starts the  
11 threads of the screws. While a single flute 24 is illustrated,  
12 it will be understood by those skilled in the art that  
13 additional flutes can be formed in cutting shank 20, as long as  
14 the edges are rounded or dull at tip 23 to prevent cutting  
15 through cortical bone.

16  
17 Still referring to FIGS. 2-4, drill bit 10 is attached to  
18 inserter 12 by attachment head 22. Attachment head 22 includes  
19 an attachment shank 30 extending from a portion 32 terminating  
20 the flared end of cutting shank 20. Attachment shank 30 has a  
21 smaller diameter than portion 32, and is divided by an  
22 enlargement 33 forming a groove 34 adjacent portion 32.  
23 Enlargement 33 also has a smaller diameter than portion 32.

24  
25 Inserter 12 includes a receiver 40 and a securing sleeve  
26 42. Receiver 40 has a shank end 43 for receipt within the  
27 chuck of a drill, and a receiver end 44 with a slot 45 formed

1     therein. A shoulder 47 is formed between the greater diameter  
2     receiver end 44 and the lesser diameter shank end 43.  
3     Attachment shank 30 is fitted to be received by slot 45. In  
4     the preferred embodiment, attachment shank 30 includes  
5     flattened sides which lie flush with the sides of slot 45.  
6     Thus, relative rotation between drill bit 10 and receiver 40 is  
7     prevented. Various structures and shapes can be employed for  
8     attachment shank 30 so as to prevent relative rotation with  
9     receiver 40. With momentary reference to FIG. 5, another  
10    embodiment of an attachment shank 30' is illustrated. In this  
11    embodiment, only a single side has been flattened to prevent  
12    relative rotation. It will be understood by those skilled in  
13    the art that notches, slots, tabs, indents and various other  
14    shapes can be employed.

15  
16         Referring back to FIGS. 2-4, securing sleeve 42 is  
17    generally tubular and has an outer diameter generally the same  
18    as the diameter of portion 32 or slightly less, thereby  
19    eliminating any protrusions likely to snag during insertion of  
20    the device. The inner diameter of securing sleeve 42 is large  
21    enough to accommodate receiver end 44 of receiver 40. An open  
22    end 50 of sleeve 42 terminates in an inwardly directed flange  
23    52 and an opposing end 53 is closed by a stop 54 having an  
24    aperture 55 formed therein. Open end 50 is received over  
25    receiver 40 and engages drill bit 10 with flange 52 received in  
26    groove 34. Shank end 43 passes through aperture 55. Receiver  
27    40 is prevented from being removed from end 53 by the



1 engagement of shoulder 47 against stop 54. Shoulder 57 has a  
2 larger diameter than aperture 55.

3  
4 Thus, receiver 40 and sleeve 42 interact to form inserter  
5 12, firmly attaching drill bit 10 to a drill but allowing a  
6 toggle or pivoting movement of drill bit 10 due to the multiple  
7 connections. The toggling action of drill bit 10 permits it to  
8 conform to the slight angle adjustments needed to remain within  
9 the intermedullary canal and not exit through the wall of  
10 pedicle 15 during drilling.

11  
12 Turning now to FIG. 6, other embodiments of a drill bit 60  
13 and an inserter 62 are illustrated. In this embodiment, drill  
14 bit 60 is generally identical to drill bit 10, with a different  
15 attachment head 63. Attachment head 63 includes a socket 64  
16 formed therein. Socket 64 can have numerous shapes such as  
17 square, triangular, etc., but is preferably a hex shape.  
18 Inserter is a single length having a receiver end 65 shaped to  
19 be received within socket 64 and a chuck end, not shown,  
20 identical to chuck end 43. The loose connection between socket  
21 64 and receiver end 65 permits toggling of drill bit 60.

22  
23 Referring to FIG. 7, a drill bit 110 and inserter 112 are  
24 illustrated. Drill bit 110 includes a cutting shank 120 having  
25 an attachment head 122 at one end and a tip 123 at an opposing  
26 end. Cutting shank 120 flares proximate attachment head 122,  
27 to substantially match the diameter thereof. At least one

1 flute 124 extends the length of cutting shank 120 from tip 123  
2 to attachment head 122. Flute 124 has a sharp edge 125  
3 extending its entire length except at tip 123. Both edges of  
4 flute 124 can be sharp if desired. Rounded or dull edges 127  
5 are formed at tip 123. The transition between sharp edge 125  
6 and dull edges 127 is preferably located at point 128 where  
7 cutting shank 120 reaches a uniform width. Sharp edge 125 can  
8 start further back toward attachment head 122, as described in  
9 the previous embodiment. Drill bit 110 to this point is  
10 generally identical to drill bit 10 and operates in the same  
11 manner.

12  
13 Still referring to FIG. 7, drill bit 110 is attached to  
14 inserter 112 by attachment head 122. Attachment head 122  
15 includes an attachment shank 130 extending from a portion 132  
16 terminating the flared end of cutting shank 120. Attachment  
17 shank 130 has a smaller diameter than portion 132, and is  
18 divided by an enlargement 133 forming a groove 134.  
19 Enlargement 133 also has a smaller diameter than portion 132.

20  
21 Inserter 112 includes a receiver 140 and a securing sleeve  
22 142. Receiver 140 has a shank end 143 for receipt within the  
23 chuck of a drill, and a receiver end 144 with a pair of tines  
24 145 extending therefrom. Attachment shank 130 is fitted to be  
25 received between tines 145. In this embodiment, attachment  
26 shank 130 includes flattened sides which are captured between

1 tines 145. Thus, relative rotation between drill bit 110 and  
2 receiver 140 is prevented.

3

4 Securing sleeve 142 is generally tubular and has an  
5 attachment end 150 from which extend a pair of tines 151  
6 terminating in inwardly directed flanges 152 and an opposing  
7 end 153. Securing sleeve 142 has an inner diameter large  
8 enough to accommodate receiver 140 inserted through attachment  
9 end 150. Removal of receiver 140 through end 153 is prevented  
10 by tines 145 engaging attachment end 150. Tines 151 are  
11 positioned between tines 145 and engage groove 134 of drill bit  
12 110. Shank end 143 passes through opposing end 153.

13

14 As with the previous embodiments, receiver 140 and sleeve  
15 142 interact to form inserter 112, firmly attaching drill bit  
16 110 to a drill but allowing a toggle or pivoting movement of  
17 drill bit 110 due to the multiple loose connections.

18

19 Various changes and modifications to the embodiments  
20 herein chosen for purposes of illustration will readily occur  
21 to those skilled in the art. To the extent that such  
22 modifications and variations do not depart from the spirit of  
23 the invention, they are intended to be included within the  
24 scope thereof which is assessed only by a fair interpretation  
25 of the following claims.

1           Having fully described the invention in such clear and  
2   concise terms as to enable those skilled in the art to  
3   understand and practice the same, the invention claimed is:

## CLAIMS

1. A vertebral drill bit for forming a pathway through a pedicle into a vertebral body, comprising:

a cutting shank having a first end and a second end;

an attachment head at the first end of the cutting shank;

a tip at the second end of the cutting shank;

a point at which the diameter of the cutting shank at the second end begins to get smaller to form the tip;

a flute formed in the cutting shank and extending from the first end to the tip;

an edge of the flute from the first end to proximate the point being sharp for cutting; and

edges of the flute from the point to the tip being rounded.

2. A vertebral drill bit as claimed in claim 3 wherein the attachment head includes a socket formed therein.

3. A vertebral drill bit as claimed in claim 1 wherein the first end of the cutting shank is flared outwardly to a larger diameter with a corresponding outward flare in the flute and the edge of the flute from the first end to proximate the point.

4. A vertebral drill bit as claimed in claim 3 wherein the attachment head includes a portion terminating the first end and having a diameter substantially the same as the larger diameter of the flared first end.

5. A vertebral drill bit as claimed in claim 4 wherein the attachment head includes a socket formed therein.

6. A vertebral drill bit as claimed in claim 4 wherein the attachment head further includes an attachment shank extending from the portion, the attachment shank divided by a groove.

7. A vertebral drill bit as claimed in claim 4 wherein the attachment head further includes an attachment shank extending from the portion, the attachment shank divided by an enlargement forming a groove adjacent the portion.

8. A vertebral drill bit as claimed in claim 1 further including an inserter for coupling the drill bit to a drill.

9. A vertebral drill bit as claimed in claim 8 wherein the inserter includes a chuck end and a receiver end.

10. A vertebral drill bit as claimed in claim 8 wherein the inserter includes a receiver received within a securing sleeve.

11. A vertebral drill bit as claimed in claim 10 wherein the receiver includes an end coupled to the attachment head preventing relative rotation between the drill bit and the receiver and the securing sleeve including means for gripping the attachment head.

12. A vertebral drill bit for forming a pathway through a pedicle into a vertebral body, comprising:

a cutting shank having a first end and a second end;

an attachment head including a portion terminating the first end of the cutting shank and having an enlarged diameter;

a tip at the second end of the cutting shank;

a point at which the diameter of the cutting shank at the second end begins to get smaller to form the tip;

a flute formed in the cutting shank and extending from the first end to the tip;

an edge of the flute from the first end to proximate the point being sharp for cutting;

edges of the flute from the point to the tip being rounded; and

an inserter engaging the attachment head for coupling the drill bit to a drill.



13. A vertebral drill bit as claimed in claim 12 wherein the attachment head includes a socket formed therein and the inserter includes a chuck end receivable by a chuck of a drill and a receiver end inserted into the socket.

14. A vertebral drill bit as claimed in claim 12 wherein the attachment head further includes an attachment shank extending from the portion, the attachment shank divided by an enlargement forming a groove adjacent the portion.

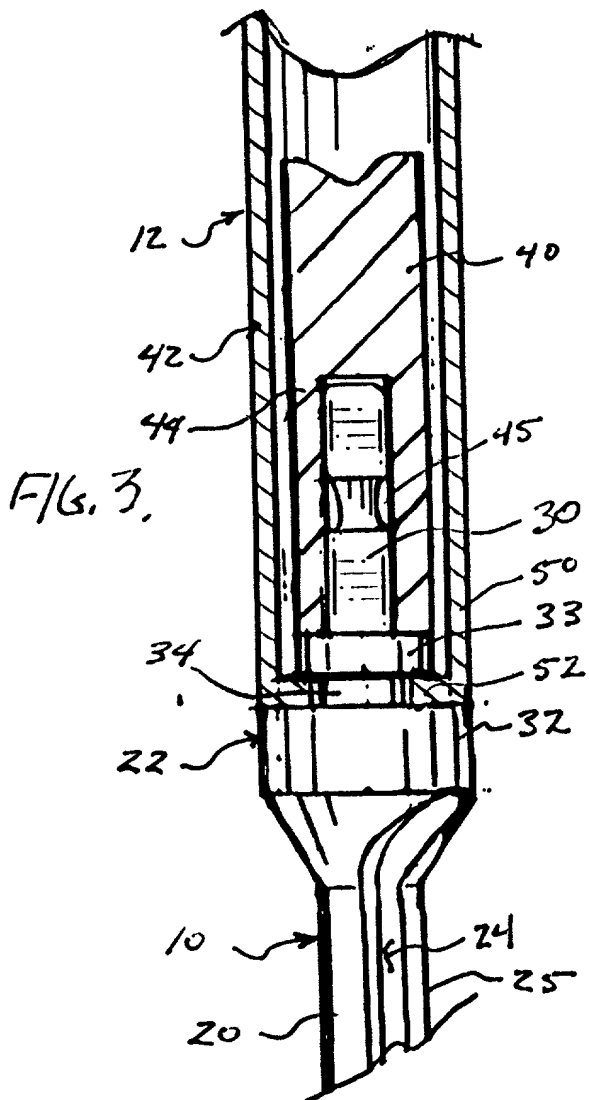
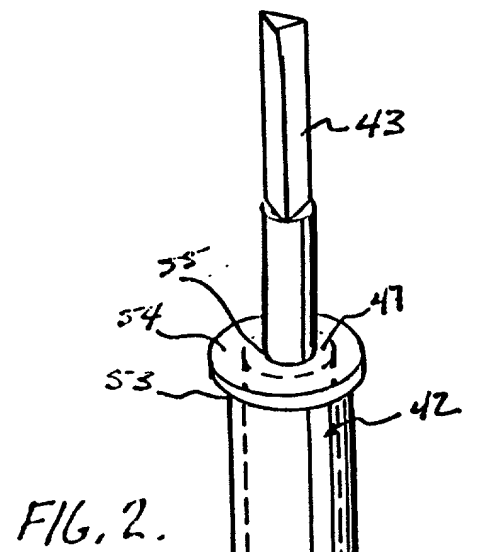
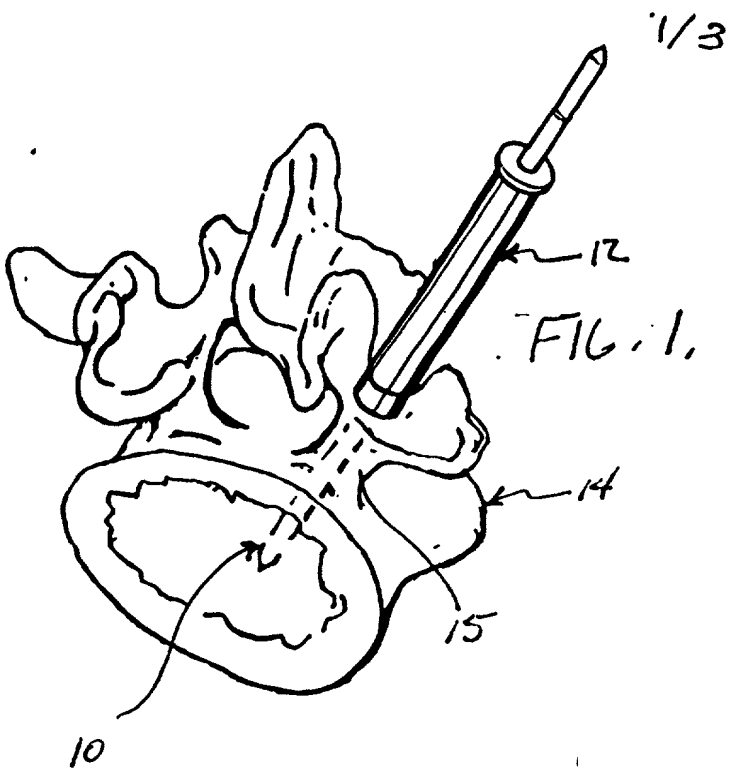
15. A vertebral drill bit as claimed in claim 14 wherein the inserter includes a receiver received within a securing sleeve.

16. A vertebral drill bit as claimed in claim 15 wherein the receiver includes an end coupled to the attachment head preventing relative rotation between the drill bit and the receiver and the securing sleeve including an inwardly directed flange at one end inserted into the groove for gripping the attachment head.

17. A vertebral drill bit as claimed in claim 12 wherein the first end of the cutting shank is flared outwardly to a larger diameter with a corresponding outward flare in the flute and the edge of the flute from the first end to proximate the point.

ABSTRACT

A vertebral drill bit for forming a pathway through a pedicle into a vertebral body. The vertebral drill bit includes a cutting shank having a generally uniform diameter, an attachment head at one end of the cutting shank and a tip at the other end of the cutting shank. Also included is a point at which the diameter of the cutting shank at the second end begins to get smaller to form the tip. A flute is formed in the cutting shank and extends from the end to the tip. An edge of the flute from the first end to proximate the point is sharp for cutting, while edges of the flute from the point to the tip are rounded.







DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled *VERTEBRAL DRILL BIT AND INSERTER* (RAP Docket Number 4042-A3) the specification of which:

  x   is attached hereto.

           was filed on                                  as Application

Serial No.                      and was amended on                                   
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to the examination or patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
			Yes	No
<u>          </u> (Number)	<u>          </u> (Country)	<u>          </u> (Day/Mo./Yr. Filed)		
<u>          </u> (Number)	<u>          </u> (Country)	<u>          </u> (Day/Mo./Yr. Filed)	Yes	No
<u>          </u> (Number)	<u>          </u> (Country)	<u>          </u> (Day/Mo./Yr. Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States Application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Applic. S/N) (Filing Date) (Status--pend., pat., abandoned)

(Applic. S/N) (Filing Date) (Status--pend., pat., abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

#### POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

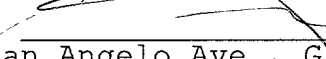
Robert A. Parsons, Reg. No. 32,713  
Michael W. Goltry, Reg. No. 39,692

Send correspondence to:

Robert A. Parsons  
PARSONS & GOLTRY  
340 East Palm Lane  
Suite 260  
Phoenix, Arizona 85004

Direct Telephone Calls to: Robert A. Parsons  
(602) 252-7494

Full name of sole or first inventor: Terry L. Ray

Inventor's signature  Date 9-21-00  
Residence: 1118 E. San Angelo Ave., Gilbert AZ 85234

Citizenship: USA  
Post Office Address: SAME AS ABOVE